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PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Eidenschink
Application No.:	10/628998
Filed:	July 28, 2003
For:	Variable Manipulative Strength Catheter
Examiner:	Catherine S. Williams
Group Art Unit:	3763

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Docket No.: S63.2-10692-US01

## FACSIMILE TRANSMITTAL LETTER

TO: Examiner Catherine S. Williams

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Respectfully Submitted,

VIDAS, ARRETT &amp; STEINKRAUS, P.A.

Date: October 30, 2006

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Application No.:	10/628938
Filed:	July 28, 2003
For:	Variable Manipulative Strength Catheter
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## APPEAL BRIEF

This is a Appeal Brief for the above-identified application in which claims 1-8, 12-13, 17-18, 20-21, 24-25 and 33-38 were finally rejected and claims 9-11, 15, 16, 22 and 23 were allowed and objected to in a Final Office Action mailed May 31, 2006. Claims 14 and 26-32 were withdrawn in the Non-final Office Action of June 2, 2005. Claim 19 was canceled in the Amendment filed September 6, 2005. Currently, claims 1-13, 15-18, 20-25, and 33-38 are pending in the application.

A Notice of Appeal was filed in this case on September 12, 2006. The fees required under §1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

A copy of the claims on appeal is presented in the Claims Appendix below.

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**(C) Real Party in Interest**

The Application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

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**(D) Related Appeals and Interferences**

At present there are no related appeals or interferences.

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**(E) Status of Claims**

In the final Office Action of May 31, 2005, claims 1-8, 12-13, 17-18, 20-21, 24-25 and 33-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. 4,822,345 to Danforth in view of 6,464,683 to Samuelson and are the subject of this appeal.

In the final Office Action of May 31, 2005, claims 9-11, 15-16, 22-23 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In the non-final Office Action of June 2, 2005, claims 14 and 26-32 were withdrawn as being directed toward an unelected species.

In the Amendment submitted September 6, 2005, claim 19 was canceled.

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**(F) Status of Amendments**

Subsequent to the Final Office Action of May 31, 2006, Applicant filed an Amendment After Final and request for reconsideration on July 31, 2006. In the Advisory Action of August 29, 2006 the Examiner indicated that the proposed amendment to the specification in the Amendment After Final of July 31, 2006 would not be entered because it was not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

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**(G) Summary of Claimed Subject Matter**

A summary of representative claims and a non-limiting listing of locations where support may be found [bracketed citations] is provided as follows:

Independent claim 1 recites a catheter assembly comprising a catheter (10) having a length that extends distally from a proximal end. The catheter (10) comprises an inner shaft (12) constructed of at least three layers (21, 23, 25), a lumen wall (29), and an outer shaft (18), and at least one heat transmitting mechanism [pg. 6, line 30 to pg. 7, line 9; pg. 8, lines 20-22; pg. 6, line 19; pg. 8, lines 8-13]. The at least one heat transmitting mechanism comprises at least one fluid transmission lumen (20) defined by a lumen wall (29) positioned between the inner shaft (12) and the outer shaft (18) [pg. 8, lines 20-22]. At least one portion of at least one of the inner shaft (12) and the outer shaft (18) of the catheter (10) has a predetermined longitudinal stiffness and the at least one portion has a predetermined temperature, so that the predetermined longitudinal stiffness is changed when the predetermined temperature is changed [pg. 3, lines 5-19; pg. 7, lines 12-14].



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**(H) Grounds of Rejection to be Reviewed on Appeal**

1. Whether the Examiner erred in rejecting claims 1-8, 12-13, 17-18, 20-21, 24-25 and 33-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. 4,822,345 to Danforth in view of 6,464,683 to Samuelson.

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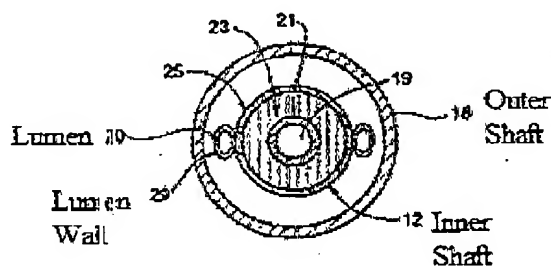
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(I) Argument

1. The Examiner erred in rejecting claims 1-8, 12-13, 17-18, 20-21, 24-25 and 33-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. 4,822,345 to Danforth in view of 6,464,683 to Samuelson.

In the Final Office Action, claims 1-8, 12-13, 17-18, 20-21, 24-25 and 33-38 were rejected under 35 USC 103(a) as being unpatentable over Danforth (4,822,345) in view of Samuelson (6,464,683). Independent claim 1 recites "the catheter comprising an inner shaft ... a lumen wall, and an outer shaft, and at least one heat transmitting mechanism, the at least one heat transmitting mechanism comprising at least one fluid transmission lumen defined by a lumen wall, the lumen wall positioned between the inner shaft and the outer shaft" (emphasis added). The elements of instant independent claim 1 are illustrated, for example, in annotated Fig. 4 of the instant application, provided below.



**Fig. 4**

As shown above in annotated Fig. 4, the catheter has an outer shaft 18 and an inner shaft 12. As known in the art, the outer shaft 18 and the inner shaft 12 define a lumen. Within that lumen there is at least one heat transmitting mechanism. The at least one heat

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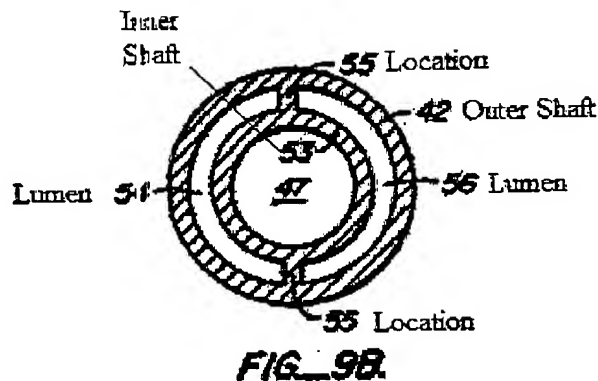
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transmitting mechanism comprises at least one fluid transmission lumen 20 defined by a lumen wall 29. The lumen wall 29 is positioned between the outer shaft 18 and the inner shaft 12. Thus, the catheter comprises an inner shaft 12, a lumen wall 29, and an outer shaft 18, and at least one fluid transmission lumen 20 defined by a lumen wall 29, the lumen wall 29 positioned between the inner shaft 12 and the outer shaft 18, as recited in instant independent claim 1.

Applicant asserts that Danforth does not teach or suggest at least one heat transmitting mechanism comprising at least one fluid transmission lumen defined by a lumen wall positioned *between* the inner shaft and the outer shaft, as recited in instant independent claim 1. As shown in annotated Fig. 9B of Danforth, provided below, the catheter has an outer shaft 42, an inner shaft 53 and two locations 55 that couple the outer shaft 42 and the inner shaft 53 together. The outer shaft 42, the inner shaft 53 and locations 55 define lumens 54 and 56. Note that neither lumen 54 nor lumen 56 has at least one fluid transmission lumen defined by a lumen wall positioned between the outer shaft 42 and the inner shaft 53. Therefore, Danforth does not teach or suggest a "catheter comprising an inner shaft ... a lumen wall, and an outer shaft, and at least one heat transmitting mechanism, the at least one heat transmitting mechanism comprising at least one fluid transmission lumen defined by a lumen wall, the lumen wall positioned between the inner shaft and the outer shaft," as recited in instant independent claim 1.

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Samuelson, like Danforth, does not teach or suggest a lumen wall, defining a fluid transmission lumen, positioned between the inner shaft and the outer shaft, as recited in instant independent claim 1. Adding the inner shaft having three layers of Samuelson to Danforth does nothing to address the failure of Danforth to teach or suggest all the elements of instant independent claim 1 from which claims 2-8, 12, 13, 17-18, 20-21, 24-25 and 33-38 depend. Applicant requests reversal of the Examiner's rejection and asserts that claim 1 is patentable over Danforth in view of Samuelson. Because independent claim 1 is patentable over Danforth in view of Samuelson, claims 2-8, 12, 13, 17-18, 20-21, 24-25 and 33-38, which depend upon instant independent claim 1 are also patentable and in condition for allowance.

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### CONCLUSION

Instant claims 1-8, 12-13, 17-18, 20-21, 24-25 and 33-38 are patentably distinct over Danforth in view of Samuelson. Instant claims 9-11, 15-16, 22-23 which were objected to by Examiner for being dependent upon a rejected base claim are patentable in their current form. Consequently reversal of the rejection and objection is respectfully requested.

Respectfully submitted,

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Date: October 30, 2006

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**(J) Claims Appendix**

Claim 1. (Previously presented) A catheter assembly comprising:

a catheter, the catheter having a length that extends distally from a proximal end, the catheter comprising an inner shaft constructed of at least three layers, a lumen wall, and an outer shaft, and at least one heat transmitting mechanism, the at least one heat transmitting mechanism comprising at least one fluid transmission lumen defined by a lumen wall, the lumen wall positioned between the inner shaft and the outer shaft,

at least one portion of at least one of the inner shaft and the outer shaft of the catheter having a predetermined longitudinal stiffness, the at least one portion having a predetermined temperature, the predetermined longitudinal stiffness being changed when the predetermined temperature is changed.

Claim 2. (Original) The assembly of claim 1 wherein the at least one heat transmitting mechanism extends distally from the proximal end along the length of the catheter to a position adjacent to the at least one portion, at least a portion of the at least one heat transmitting mechanism constructed and arranged to conductively change the predetermined temperature of the at least one portion.

Claim 3. (Previously presented) The assembly of claim 1 the at least one fluid transmission lumen constructed and arranged to transport a fluid having a temperature different than the predetermined temperature of the at least one portion from the proximal end of the catheter to the position adjacent to the at least one portion.

Claim 4. (Original) The assembly of claim 3 wherein the fluid has a temperature greater than that of the predetermined temperature of the at least one portion.

Claim 5. (Original) The assembly of claim 4 wherein the at least one heat transmitting mechanism is constructed and arranged to conductively transmit heat from the fluid to the at least one portion.

Claim 6. (Original) The assembly of claim 3 wherein the fluid has a temperature less than that of the predetermined temperature of the at least one portion.

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Claim 7. (Original) The assembly of claim 6 wherein the at least one heat transmitting mechanism is constructed and arranged to conductively transmit heat from the at least one portion to the fluid.

Claim 8. (Previously presented) The assembly of claim 1 further comprising a fluid source in fluid communication with the at least one fluid transmission lumen.

Claim 9. (Previously presented) The assembly of claim 1 wherein the lumen wall is at least partially constructed from at least one material selected from the group consisting of polyamide, copolymer polyolefin, polyethylene, and any combination thereof.

Claim 10. (Previously presented) The assembly of claim 1 the lumen wall having a thickness of about 0.002 inches or less.

Claim 11. (Previously presented) The assembly of claim 1 the lumen wall having a thickness of about 0.001 inches or less.

Claim 12. (Previously presented) The assembly of claim 1 wherein the at least one fluid transmission lumen has an inner diameter of about 0.002 inches to about 0.008 inches.

Claim 13. (Previously presented) The assembly of claim 1 wherein the at least one fluid transmission lumen has an inner diameter of about 0.003 inches.

Claim 14. (Withdrawn) The assembly of claim 9 wherein the lumen wall is at least partially contained within the inner shaft.

Claim 15. (Original) The assembly of claim 9 wherein the lumen wall is immediately adjacent to the inner shaft.

Claim 16. (Original) The assembly of claim 9 wherein the lumen wall is immediately adjacent to the outer shaft.

Claim 17. (Original) The assembly of claim 3 wherein the fluid is a liquid.

Claim 18. (Previously presented) The assembly of claim 1 wherein the at least one portion of at least one of the inner shaft and the outer shaft of the catheter is at least partially constructed from a member of the group consisting of polyethylene (LDPE), high density polyethylene (HDPE), ionomer and a polymer ether block amide, one or more liquid crystal polymers, one or more ionomers, polytetrafluoro-ethylene (PTFE) and any combination thereof.

Claim 19. (Cancelled)

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Claim 20. (Previously presented) The assembly of claim 1 wherein the at least three layers comprise:

a first layer, the first layer defining a guide wire lumen, the first layer being at least partially constructed from HDPE

Claim 21. (Previously presented) The assembly of claim 20 wherein the at least three layers comprise:

a second layer of anhydride modified linear low density polyethylene, the first layer being engaged to the second layer.

Claim 22. (Previously presented) The assembly of claim 21 wherein the at least three layers comprise:

a third layer, the third layer at least partially constructed of at least one third layer material exhibiting an order/disorder transformation during a change in the temperature of the at least one third layer.

Claim 23. (Previously presented) The assembly of claim 22 wherein the at least one third layer material is selected from at least one member of the group consisting of polyether block amide, LCP, copolymer polyolefin, and any combination thereof.

Claim 24. (Original) The assembly of claim 1 further comprising a balloon, the balloon being engaged to at least a portion of at least one of the inner shaft and outer shaft.

Claim 25. (Original) The assembly of claim 24 wherein at least a portion of the balloon defines a stent mounting region.

Claim 26. (Withdrawn) The assembly of claim 1 wherein the at least one heat transmitting mechanism comprises at least one electrically conductive member and at least one at least one heating element positioned adjacent to the at least one portion.

Claim 27. (Withdrawn) The assembly of claim 26 wherein the at least one electrically conductive member extending from the at least one heating element to a source of electrical current positioned adjacent to the proximal end of the catheter, the at least one electrically conductive member in selective electronically conductive communication with the source of electric current and the at least one heating element.

Claim 28. (Withdrawn) The assembly of claim 27 wherein when an electric current is communicated to the at least one heating element, the at least one heating element produces heat.



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Claim 29. (Withdrawn) The assembly of claim 28 wherein the at least one heat transmitting mechanism is constructed and arranged to conductively transmit heat from the at least one heating element to the at least one portion.

Claim 30. (Withdrawn) The assembly of claim 29 wherein the at least one heat transmitting mechanism further comprises at least one fluid transmission lumen, the at least one fluid transmission lumen constructed and arranged to transport a fluid having a temperature different than the predetermined temperature of the at least one portion from the proximal end of the catheter to the position adjacent to the at least one portion.

Claim 31. (Withdrawn) The assembly of claim 30 wherein the fluid has a temperature less than that of the predetermined temperature of the at least one portion.

Claim 32. (Withdrawn) The assembly of claim 31 wherein the at least one fluid transmission lumen conductively transmits heat from the at least one portion to the fluid.

Claim 33. (Previously presented) The assembly of claim 1 wherein the temperature of the fluid is at least about 10 degrees Celsius warmer than human body temperature.

Claim 34. (Previously presented) The assembly of claim 1 wherein the temperature of the fluid is at least about 10 degrees Celsius cooler than human body temperature.

Claim 35. (Previously presented) The assembly of claim 1 wherein the temperature of the fluid is at least about 25 degrees Celsius cooler than human body temperature.

Claim 36. (Previously presented) The assembly of claim 1 wherein the temperature of the fluid is about 50 degrees Celsius to about 60 degrees Celsius.

Claim 37. (Previously presented) The assembly of claim 1 wherein the temperature of the fluid is about 15 degrees Celsius to about -195 degrees Celsius.

Claim 38. (Previously presented) The assembly of claim 1 wherein the fluid is at least partially comprised of Nitrous Oxide.

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(K) Evidence Appendix - None

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(L) Related Proceedings Appendix - None

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